



PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/781,179  
Applicant : Anthony William Sly  
Filed : February 18, 2004  
TC/A.U. : 1614  
Title : Ophthalmic Fluid  
  
Docket No. : 283702-14-1 (D5053-00031)  
Customer No. : 08933

CERTIFICATE OF MAILING,  
37 C.F.R. § 1.8(a)

I certify that this correspondence and the enclosures mentioned therein are being deposited by First Class U.S. Mail with sufficient postage on the date shown below, addressed to Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22314-5014.

*Richard A. Packoff*  
Richard A. Packoff, Reg. No. 34,807

10/17/05  
RAC

**DECLARATION OF ANTHONY W. SLY**  
**PURSUANT TO 37 C.F.R. § 1.132**

I hereby declare as follows:

1. I am the same Anthony W. Sly who is named as the inventor of the invention described and claimed in the patent application referenced above.
2. I have reviewed the Ding et al. reference, U.S. Patent No. 5,981,607 cited by the Examiner in the Office Action in the patent application referenced above.
3. Note that the present invention is directed to treating Contact Lens Intolerance (CLI), whereas Ding et. al. is concerned with treatment of KCS (Kerato Conjunctivitis Sicca).
4. As will be explained in more detail below, in Ding et. al., each droplet of triglyceride will be surrounded by adsorbed surfactants. This leads to repulsion between the droplets in the emulsion, preventing them spreading out into a uniform layer.
5. In KCS, the sufferer has difficulty producing a tear film, which leads to the dry eye symptoms as discussed in Ding et. al. However, with CLI, the sufferer has difficulty maintaining a uniform lipid layer over the tear film and the contact lens. If the lipid layer is compromised in any way the tear film evaporates much more quickly than is normal. The use of

**PATENT**

the triglyceride layer in the present invention enhances the protection normally provided by the lipid layer.

6. A monolayer of triglycerides is formed by the effective bonding between the polar hydrophilic triglyceride head and nonpolar hydrophobic tail. In their pure state, the triglycerides adhere to each other in cohesive micelles. As concentration increases, lipid micelles (a) become crowded together, and coalesce into extended rods (b), then hexagonal aggregates of such rods (c), and finally into an aggregation pattern of significance - the bilayers (d). Like micelles, these are stabilized partly by internal van der Waals bonding between adjacent hydrocarbon tails and partly by polar interactions.

7. As disclosed in Ding et al., the combination of polysorbate 80 (surfactant) and Pemulen® (emulsion thickening agent), followed by agitation, generate short range repulsions, which help to stabilize emulsion droplets. On forming oil/water emulsions, Pemulen molecules form an adsorbed gel layer around each droplet, with the hydrophobic portions of the polymer anchored in the oil phase. Thus, when two oil droplets approach each other, a physical repulsive force is generated by the presence of these adsorbed layers.

8. If the oil droplets or the substrate are covered by a surfactant, as in emulsion systems, surfactant molecules from the continuous phase can be adsorbed into the substrate. Consequently, the droplet does not spread on the substrate if surfactant layers repel each other. This is why oil droplets stabilized in water by traditional surfactants do not spread on hydrophobic substrates. The surfactant encapsulated oil micelle also has relevance when considering the resident tear film lipid layer of the Kerato Conjunctivitis Sicca (KCS) sufferer, where free surfactant molecules are adsorbed by the tear film lipids and the contact lens matrix, thereby decreasing the lipid integrity adhesion and cohesion stability, disabling the required

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smooth refractive surface, and ultimately increasing dehydration of the lens and evaporation of the aqueous phase of the tear film.

9. Therefore, based on the above discussion, a lipid monolayer cannot form in the presence of the surfactants polysorbate 80 and Pemulen, and the teachings of Ding et al. would be inoperative for purposes of the presently claimed invention.

10. I have recognized Contact Lens Intolerance (CLI) as a condition resulting from the typical application of a contact lens onto the eye surface which manifests as ocular irritation, tear film disruption, discomfort and onset dry eye symptoms. In the present invention, the application of neat triglycerides superficially to the contact lens provides a barrier of hydrophobic integrity of the lipids, creating a semi-permeable membrane intermediate the corneal surface and the contact lens. This prevents aqueous migration between the tear film and the contact lens, and the external environment. Also, contact between the lens and the eye surface is prevented, thereby obviating foreign body irritation. Ultimately, contact lens tolerance, comfort and long term experience are improved. The light passage through the lens to the retina is unaffected as the lipid layer maintains a smooth reflective surface which does not affect the lens quality. In KCS, there is a deficiency in aqueous tear secretion, so that the tear film does not cover the corneal surface evenly. Traditionally, if the lipid phase becomes reduced, evaporation of the precorneal tear film will increase. However, the lipid phase is not reduced in KCS. In CLI the subject shows a degraded lipid integrity, and normal lacrimal activity.

11. An important aspect of the present invention is the orientation of the monolayer in relation to the surface of the contact lens, as the fluid itself has a non-polar hydrophobic tail and a polar head. Lipid integrity in the formula is needed to create and maintain

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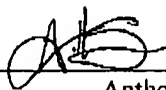
a stable and cohesive membrane and adhesion to the contact lens. The contact lens itself is of high porosity, with a negatively charged surface. The polarity has an important role in the understanding of the positioning of the monolayer matrix in relation to the contact lens surface, as the formation of the monolayer superficial to the contact lens surface fulfills the following functions: (1) forming a malleable barrier between the lens membrane and the epithelium of the eye; (2) reducing protein adsorption of the lens by intercepting the proteins; and (3) providing osmotic interference via a semi-permeable membrane.

12. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this patent application or any patent issuing thereon.

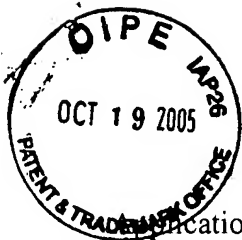
11 October 2005

Date

By:



Anthony W. Sly



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TRANSMITTAL LETTER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Enclosed for filing is:

- ☒ Amendment and Response.
- ☒ Petition for Extension of Time.
- ☒ Please charge the fee of \$60 (small entity rate) for the one-month extension to Deposit Account No. 04-1679. This Transmittal Letter is submitted in duplicate.
- ☒ Please charge any additional fees or credit any overpayments to Deposit Account No. 04-1679. This Transmittal Letter is submitted in duplicate.
- ☒ Other: Return postcard.

Respectfully submitted,

Date: 10/17/05

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<p>CERTIFICATE OF MAILING, 37 C.F.R. §1.8(a)</p> <p>I certify that this correspondence and the enclosures mentioned therein are being deposited by First Class U.S. Mail with sufficient postage on the date shown below, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p> <p><u>Richard A. Paikoff</u> Richard A. Paikoff, Reg. No. 34,892</p> <p><u>10/17/05</u> Date</p>
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